

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

<p>SANDOZ, INC., <i>et ano.</i>,</p> <p style="text-align: center;">Plaintiffs,</p> <p style="text-align: center;">v.</p> <p>UNITED THERAPEUTICS CORP., <i>et ano.</i>,</p> <p style="text-align: center;">Defendants.</p>	<p>Civil Action No.: 19-cv-10170</p> <p style="text-align: center;">OPINION AND ORDER OF THE SPECIAL DISCOVERY MASTER REGARDING CONFIDENTIALITY OF SMITHS SETTLEMENT TERM SHEET</p>
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LINARES, J.

This matter comes before the Special Master by way of a Letter dated February 19, 2021 from counsel for Defendant United Therapeutics Corporation (“UTC”) regarding the confidentiality designation of certain provisions of a “Binding Term Sheet” dated November 6, 2020 between defendant Smiths Medical ASD, Inc. (“Smiths”) and Plaintiffs Sandoz, Inc. and Raregen, LLC (“Term Sheet”). The Special Master has reviewed the submissions, including the February 26, 2021 Response from Plaintiffs, and the relevant controlling law. For the reasons set forth below, the Special Master hereby denies the relief requested by UTC.

I. DISCUSSION

The Special Master presumes that the parties are familiar with the facts surrounding the underlying action and claims. Accordingly, the Special Master will only recite the relevant procedural and factual background necessary to dispose of the dispute at hand.

The Term Sheet, which is marked “Subject to FRE 408; Settlement Agreement,” states that it constitutes the binding agreement between Plaintiffs and Smiths “to resolve and settle the

litigation between Plaintiffs and Smiths” – the “litigation” being the instant litigation. Plaintiffs have designated certain portions of the Term Sheet as “Highly Confidential” under the Stipulated Confidentiality Order entered on June 6, 2019 (Docket 55). UTC objects to Plaintiffs over-designation of certain portions of the Term Sheet as “Highly Confidential”, arguing that only limited provisions relating to price, quantity and timing should be redacted as “Highly Confidential.”¹

The Confidentiality Order provides, in relevant part:

The term "Protected Information" shall include all Materials designated as "CONFIDENTIAL" or "HIGHLY CONFIDENTIAL," as those terms are defined herein, that the Source believes constitutes, discloses or relates to confidential or proprietary business information; processes, operations, research, technical or developmental information, testing, and studies relating to drug products; competitively sensitive financial and strategic information and internal financial projections; and production, marketing, sales, shipments, or other proprietary data or information of commercial value, including trade secrets.

[. . .]

"HIGHLY CONFIDENTIAL" shall mean Protected Information of a most sensitive nature that might be of significant value to an actual or potential competitor of the Source and the disclosure of which could reasonably place the Source at a competitive disadvantage. Examples of categories of such "HIGHLY CONFIDENTIAL" Protected Information include: documents and things relating to, constituting or reflecting competitively sensitive financial results, planning, and strategic information; trade secrets; agreements with customers, distributors, or vendors; business plans; the research and development (including the discovery and development of a party's product(s), product formulation, manufacturing, trials, testing, and related materials) of any product; 510(k) submissions, approved and non-approved regulatory claims, design specifications, certification details, certificate expirations, regulatory findings, complaint details, mandatory reported incidents, CAPA's and design changes; non-

¹ The information Plaintiffs have designated and redacted as “Highly Confidential” are highlighted in green in Exhibit A to UTC’s February 19, 2021 Letter, while UTC’s more limited proposed redactions appear in orange.

public patent applications; and projected future sales, pricing, revenue, cost, or profit information for any products.

UTC argues that Plaintiffs have over-designated certain portions of the Term Sheet as “Highly Confidential” and that only certain limited sections relating to pricing, quantity and timing should properly be redacted as “Highly Confidential.” UTC argues that these more limited redactions are consistent with the parties’ prior practice with respect to other commercial contracts that have been produced in discovery, including supply agreements between Smiths and UTC, in which only information relating to dollar amounts for pricing, specific quantities of product and identities of customers were redacted. UTC further argues that the effect of this over-designation by Plaintiffs prevents it from sharing relevant information in the Term Sheet with in-house UTC lawyers, who are knowledgeable about the import of such provisions. Finally, UTC argues that the information that is redacted is relevant to UTC’s defense that Plaintiffs could have entered into written contracts to secure or obtain regulatory clearance for a cartridge or a pump years ago.

Plaintiffs argue the information it has designated as “Highly Confidential” falls within the express definition under the Confidentiality Order and the examples listed therein, and thus the designations are proper. Plaintiffs also argue that the confidentiality level of other supply or commercial agreements produced in this action are different from and not comparable to the settlement Term Sheet here, and further, how the parties agreed to handle prior confidentiality designations in other agreements is not determinative of whether the designations in the settlement Term Sheet are proper.

The Special Master agrees with the Plaintiffs and holds that the information Plaintiffs have designated as “Highly Confidential” in the Term Sheet shall remain so designated. The information designated by Plaintiffs falls within the definition of “Highly Confidential” in the

Confidentiality Order and the examples cited therein, including planning and strategic information, business plans, 510(k) submission and regulatory findings. The Confidentiality Order, in addition to being a court order, is a negotiated agreement between the parties that must be enforced according to its terms. The parties agreed to include specific examples of the type of information that qualifies for “Highly Confidential” protection – the information Plaintiffs have designated in the Term Sheet falls within the plain meaning of the Confidentiality Order. In addition, any prior practice of the parties with respect to treatment of confidential information in other unrelated commercial agreements is not determinative of the issue here, and certainly does not constitute a waiver of any party’s right to designate information as “Highly Confidential” in any subsequent and unrelated agreement. Accordingly, the Special Master holds that Plaintiffs’ designation of certain information in the Term Sheet as “Highly Confidential” is proper, and UTC’s request is denied.

II. ORDER

For the foregoing reasons, it is on this 23rd day of April 2021,

ORDERED that UTC’s request in its February 19, 2021 Letter is denied; and it is further

ORDERED that the information in the Term Sheet that Plaintiffs have designated as “Highly Confidential” under the terms of the Confidentiality Order shall be maintained as “Highly Confidential” in accordance with the Confidentiality Order.

SO ORDERED.

/s/ Jose L. Linares

Hon. Jose L. Linares, U.S.D.J. (Ret.)